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(54) Title of the Invention: Soft Capsule Agent

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SPECIFICATION

1. Title of the invention: Soft Capsule

2. Claims

1) A soft capsule, produced by blending a natural water-soluble high polymer and a hydrophilic substance in natural oil.

2) The soft capsule according to claim 1, which has Glycyrrhizae radix extract as an essential component of the hydrophilic substance.

3) The soft capsule according to claim 1, wherein the natural oil is selected from animal oil, vegetable oil or oil derived from animal or vegetable oil.

4) The soft capsule according to claim 1, wherein an organic acid and/or salt thereof is blended with said natural water-soluble high polymer.

3. Detailed description of the invention

[Field of industrial utilization]

The present invention offers a soft capsule that is composed of natural substances and does not employ synthetic preservatives or synthetic emulsifiers of any kind, which is useful in the pharmaceutical and foodstuff fields for containing substances that are strongly hydrophilic.

[Prior art] In the past, with pharmaceutical products, cosmetics, foodstuffs, and other such products, various substances in forms such as liquids, pastes, suspensions and powders have been introduced into capsules, or have been coated and molded with capsule base to produce capsules. When strongly hygroscopic or hydrophilic substance have been introduced into capsules, synthetic emulsifiers have been added.

[Problems to be solved by the invention]

There are, however, restrictions on capsule contents that can be introduced into soft capsules. It is difficult to introduce plant extracts or drugs that are hydrophilic or hygroscopic into soft capsules.

Specifically, soft capsule coatings (bases) generally have water-soluble gelatin as a primary component, making it difficult to introduce the capsule content due to dissolution or softening of the capsule coating. Specifically, when a strongly hydrophilic substance is to be introduced into a soft capsule, the water content in the content itself is transferred to the capsule coating agent, leading to modifications whereby the capsule coating agent is dissolved. Even if the water content of the hydrophilic substance, etc. is removed, the soft capsule coating will soften due to water content that permeates through the soft capsule coating agent, making it necessary to increase the thickness of the capsule coating agent. When substances such as hydrophilic substances are to be introduced into soft capsules, it is thus necessary to increase the solids content of the capsule coating agent in order to prevent elution of the content by using, for example, wheat germ oil.

When the solids content of the capsule content is increased, the fluidity of the content during packing decreases, making operations difficult.

For these reasons, the manufacturing costs of the soft capsule increase, and the disintegration properties of the capsule are compromised due to the thickening of the capsule coating agent.

In addition, when hydrophilic or other such substances are introduced into soft capsule coating agents, synthetic emulsifiers (surfactants) such as glycerin fatty acid ester, propylene glycol fatty acid ester or sorbitan fatty acid ester are used in order to emulsify or disperse the oil component in the hydrophilic or other such substance. The current state of society places an emphasis on healthful and natural products, and the use of these emulsifiers is not consistent with the current philosophy.

[Means for solving the problems]

As a result of various investigations regarding means for achieving the aforementioned objectives, the present invention was perfected upon discovering that a soft capsule that does not undergo modification or dissolution of the capsule coating agent is produced by blending in a natural oil component with a composition produced by dispersing and dissolving a natural hydrophilic high polymer material in a hydrophilic substance.

Glycyrrhizae radix extract is used as an essential component of the hydrophilic substance, and by blending in natural water-soluble polysaccharide and organic acid or salt thereof with this substance, a gel composition is obtained that has excellent fluidity, and does not allow transport of water content. A natural oil component is added to this gel composition, and the emulsified composition is then introduced into the soft capsule coating agent.

The natural water-soluble high polymer material of the present invention has no particular restrictions, provided it is a substance that has a gelling, thickening or stabilization action.

Examples of substances that can be cited include seaweed binders such as carrageenan, *fua-seran**, agar and alginate, vegetable water-soluble high polymers such as

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* phonetic spelling—Trans. Note.

guar gum, tamarind, locust bean gum, gum arabic, pectin, starch, dextrin and konnyaku mannan, and viscous high polymer materials derived from microorganisms, such as pullulan and xanthan gum. In addition, examples of animal and vegetable protein water-soluble high polymers that can be cited include casein, gelatin, soy protein and wheat gluten.

These natural water-soluble polysaccharides can be used individually or multiple types can be blended together, and it is preferable to combine substances that have a surface-tension conditioning effect. The amount of natural water-soluble high polymer material which is used is to be determined in accordance with the concentration and added amount of hydrophilic substance, and the fluidity of the content.

It is preferable to add the natural water-soluble high polymer material so that the viscosity of the gel composition that is obtained from the hydrophilic substance and natural water-soluble high polymer material is 1000 cp or greater at 30°C.

If the added amount of natural water-soluble polysaccharide is such that the viscosity of the gel composition is less than 1000 cp, then transfer of water content will tend to occur when the material is introduced into the soft capsule coating agent.

Glycyrrhizae radix extract is an essential component of the hydrophilic substance of the present invention, and other hydrophilic substances can also be combined.

It is particularly desirable for the essential component of Glycyrrhizae radix extract to be a water-soluble extract that contains flavonoids and triterpenes such as glycyrrhetic acid.

The glycyrrhetic acid which is an effective component in the Glycyrrhizae radix can be a substance that has been separated and purified.

There are no particular restrictions on the amount of Glycyrrhizae radix extract used, as amounts will differ depending on the other blended components and the components of the Glycyrrhizae radix. It is preferable, however, for glycyrrhetic acid derivatives to be present in an amount of 0.01 wt% or greater.

Examples of the hydrophilic substance of the present invention that can be cited include extracts and extract powders obtained from medicinal plants, fruit juices or seafood, as well as drugs, and raw royal jelly.

Blending organic acids or salts thereof with said natural water-soluble high polymer material has the action of stabilizing the contents and accelerating gelation. Examples that can be cited include citric acid, malic acid, tartaric acid, fumaric acid, vinegar, citrus fruit juices, and salts thereof. In addition, inorganic acids and salts thereof (e.g., phosphoric acid, trisodium phosphate) may also be used, but adding such substances is undesirable for the reasons discussed previously.

The amount of organic acid or salt thereof which is used has no particular restrictions, as an amount is used that allows stabilization of the capsule content. Preferably, an amount is used that adjusts the pH of the capsule content to 1.7-3.6.

The method for adding the organic acid and/or salt can involve addition at the same time as the natural water-soluble high polymer material.

The natural oil of the present invention is added in order to form an oil phase so that water content contained or affixed to the hydrophilic substance is not transferred to the surface of the capsule coating agent. In addition, such substances can also be blended in order to provide the pharmacological or nutritive effects possessed by the natural oil. Examples of natural oils that can be cited are animal oils, vegetable oils and oils derived from animal and vegetable oils. Examples of vegetable oils that can be cited include safflower oil, sunflower oil, evening primrose oil, coconut oil, soy oil, olive oil, jojoba oil, avocado oil and wheat germ oil. Examples of animal oils include squalene, mud turtle oil, mink oil and eel oil. Examples of oils derived from animal and vegetable oils include linolenic acid, linoleic acid, eicosapentaenoic acid and docosahexaenoic acid. It is preferable for a single natural oil to be used, but multiple types may be blended in such a manner that crystals do not precipitate at low temperatures. The amount of natural oil which is used is 2% or greater with respect to the weight of the capsule content, with 30-60 wt% being preferred. If the added amount is less than 2 wt%, the stability of the product will be poor, and water transfer will tend to occur, resulting in dissolution or modification of the capsule coating.

In addition, other additives such as vitamins for nutrient enrichment, as well as colorants and antioxidants, can also be added as desired in ranges in which the objectives of the present invention are not compromised.

The soft capsule coating agent used in the present invention has no particular restrictions, but gelatin is preferred. The amount of gelatin used is ordinarily 50-80 wt% of the total weight of the capsule coating agent. The method for manufacturing the capsule coating agent can be a common molding method.

There are no particular restrictions on the method for introducing the capsule content into the soft capsule coating agent, and manufacture can be carried out by methods such as common dipping methods, stamping methods and dripping methods.

[Working examples]

The present invention is described in additional detail below using working examples, but the present invention is not restricted to these working examples.

Working Example 1

Seven parts of Glycyrrhizae radix extract, 15 parts of Eucommia extract, 5 parts of ginseng extract and 18 parts of purified water were mixed, whereupon 2 parts of gum arabic, 6 parts of pullulan, 12 parts of dextrin and 2.5 parts of citric acid were added to this solution, and dispersed until uniform. This dispersion was then heated to 65°C to effect dissolution, 45 parts of evening primrose oil heated to 65°C were added in small quantities, and the mixture was stirred until uniform to produce the capsule content.

Meanwhile, 50 parts of purified gelatin, 15 parts of sorbitol, and 60 parts of purified water were added. The water was absorbed and swelling occurred, whereupon the material was heated to 80°C and the materials were uniformly dissolved to produce the capsule coating agent. A rotary stamping method was carried out using the prepared capsule content which was introduced and molded into the capsule coating agent, thus producing the soft capsules.

The soft capsule content weighed 400 mg, and the coating agent weighed 110 mg.

Working Example 2

The soft capsule of the present invention was produced in the same manner as in Working Example 1, with the exception that the dextrin was substituted by 11.5 parts of

microcrystalline cellulose, and that 0.5 part of tamarind *taruitai*[*] and 0.5 part of natural vitamin E was used in the 45 parts of evening primrose oil.

Working Example 3

The soft capsule of the present invention was produced in the same manner as in Working Example 1, with the exception that the evening primrose oil in Working Example 1 was substituted by 20 parts of wheat germ oil, 25 parts of eicosapentaenoic acid and 0.5 part of natural vitamin E.

Working Example 4

The soft capsule of the present invention was produced in the same manner as in Working Example 1, with the exception that 7 parts of Glycyrrhizae radix extract, 35 parts of raw royal jelly and 13 parts of purified water were dispersed and blended.

Comparative Example 1

The soft capsule of the present invention[**] was produced in the same manner as in Working Example 1, with the exception that the 7 parts of Glycyrrhizae radix extract and 2.5 parts of citric acid used in Working Example 1 were not blended in.

Comparative Example 2

Thirty-five parts of raw royal jelly and 12 parts of purified water were dispersed together, and a mixture of 45 parts of evening primrose oil and 2.5 parts of sorbitan fatty acid ester was added in small quantities to this solution. The materials were then stirred until uniform to produce the capsule content. The soft capsule of the present invention** was then obtained in the same manner as in Working Example 1.

Regarding the soft capsules of Working Examples 1-4 and Comparative Examples 1 and 2, results are presented in regard to the active water content present in the capsule

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[*] This may be a misprint for polysaccharide—Trans. Note.

[**] sic; Comparative Example?—Trans. Note.

content and the effect when stored at room temperature and 40°C (50% relative humidity (RH), change over 2 months).

Table 1

Water content of introduced material wt% [1)]		Change over time	
		Room temperature, 2 months	40°C, 2 months
Working Example 1	14.3%	No change	No change
Working Example 2	14.1%	No change	No change
Working Example 3	13.8%	No change	No change
Working Example 4	11.5%	No change	No change
Comparative Example 1	13.6%	Partial capsule deformation	Completely deformed in parts
Comparative Example 2	18.9%	No modification	Disintegration of capsule

1) Carl Fischer method

[Effect of the invention]

The soft capsule of the present invention allows introducing hydrophilic material into a soft capsule coating agent, and has the effect of expanding the range of utilization of the technology to accommodate water-soluble substances that are not stable with respect to heat. Moreover, the present invention also offers a soft capsule that satisfies market demands due to the use of completely natural substances, or substances that are derived from natural raw materials.